

REMARKS

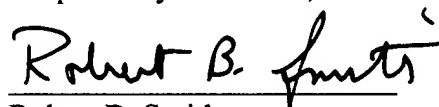
The applicants acknowledge with thanks the Examiner's careful review of the application, and the indication that claims 3-6 are allowable.

By the foregoing amendments, claim 1 has been canceled, and claims 3-6 have been written into independent form, to recite all the limitations of the parent claim (claim 1). Claim 2 has been amended to depend on claim 3. Also, several dependent claims have been added.

The specification has been amended to add section headings as required in the last Office Action, and to make several idiomatic revisions. With respect to the section headings, the applicant's respectfully point out that the version of Rule 77 reproduced in the Office Action has been amended; the applicants believe that the amendments made herein substantially comply with the current version of the rule.

In light of the foregoing amendments and remarks, favorable consideration and allowance of the application are respectfully requested.

Respectfully submitted,



Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)
(212) 735-3020

MARKED-UP VERSION TO SHOW CHANGES MADE

Changes To The Specification:

Page 1, lines 5-21:

Many types of medicine [is] are given as solutions or suspensions of a medical active substance which are subcutaneously or intramuscularly administered.

Many advantages are obtained if the solid medicine₁ instead of being dissolved or suspended₁ is formed as small needle shaped pegs which are inserted directly into the tissue where they are dissolved in the tissue fluids and in this way administered in the body. Such pegs can be given a size which is comparable [with] to the size of the needle which is used for the injection of the corresponding fluid medicine. As the medicine itself is the needle, no used needles [shall] need to be disposed of after the insertion and consequently the risk of accidental needle scratcheses is eliminated. Further₁ most medicine has a longer shelf life in a solid state than in a solution.

A problem [by] with the solid medicament pegs is their size. As they have to be sufficiently thin to be comparable with an injection needle₁ their thickness is about 1 mm or less₁ [and] And₁ to ensure a deposition in the subcutaneous layer of the skin₁ they have to be short, preferably in the interval 1 - 10 mm. Such sizes can hardly be handled without a tool such as a pincer and even with a pincer the handling is difficult especially for sight impaired people.

Page 2, lines 1 15:

WO 96/08289 also describes a device which by pressurized air accelerates the peg from a cassette through a barrel to shoot it into the skin. As it is important for diabetics that the medicament is inserted subcutaneously, a [the] device by which the peg is by a plunger followed to its subcutaneous position is preferred as being more precise than a shooting device.

Further, in the device according to WO 96/08289 no attention has been paid to the fact that the medicament is biodegradable and [have] has to be kept absolutely dry until it is implanted, i.e., the implant [have] has to be stored in a vessel which is diffusion tightly sealed.

BRIEF DESCRIPTION OF THE INVENTION

Instead of the device in WO 96/08289 by which the user presses the peg through the skin, a device is preferred by which the medicine implant [by an impact] is moved to its subcutaneous position by an impact. Such a device may comprise a socket for a cassette with medicine pegs and a hammer which can, against the force of a spring, be brought to a cocked position from which it can be released to return and hit an anvil from which the impact is transmitted to the medicine peg.

CHANGES TO THE CLAIMS

2. (Amended) A cassette according to claim [1, characterised in that]
3, wherein the medicine peg is [moulded] molded in the first bore.

3. (Twice Amended) A cassette [according to claim 1, characterised in that] for storing and insertion of a solid medicine peg, said cassette comprising at least one unit having a first bore (2) accommodating the medicine peg (3) and having a diameter corresponding to the diameter of the peg (3), a second bore (4) in coaxial extension of the first bore (2) and having a diameter larger than the diameter of the first bore (2), an inserter comprising an inserter shaft (5) fitting into the first bore (2) and a guiding head (6) connected to the inserter shaft (5) in coaxial extension of the inserter shaft and fitting into the second bore, the inserter shaft (5) having a distal end adjacent to a proximal end of the peg (3) and a proximal end connected to a distal end of the guiding head (6) which forms at its proximal end an anvil (7), the second bore (4) having a length so that the distal end of the inserter shaft (5) is moved to a position extending beyond the distal end of the housing a distance corresponding to a wanted insertion depth for the peg when the distal end of the guiding head is moved to the bottom of the second bore, wherein the head (6) of the inserter fits into the second bore with a press fitting which provides a diffusion tight sealing of the proximal end of the unit, and [that] wherein the distal end of the unit is closed by a membrane diffusion tightly sealing the distal end of the unit.

4. (Twice Amended) A cassette [according to claim 1, characterised in that] for storing and insertion of a solid medicine peg, said cassette comprising at

least one unit having a first bore (2) accommodating the medicine peg (3) and having a diameter corresponding to the diameter of the peg (3), a second bore (4) in coaxial extension of the first bore (2) and having a diameter larger than the diameter of the first bore (2), an inserter comprising an inserter shaft (5) fitting into the first bore (2) and a guiding head (6) connected to the inserter shaft (5) in coaxial extension of the inserter shaft and fitting into the second bore, the inserter shaft (5) having a distal end adjacent to a proximal end of the peg (3) and a proximal end connected to a distal end of the guiding head (6) which forms at its proximal end an anvil (7), the second bore (4) having a length so that the distal end of the inserter shaft (5) is moved to a position extending beyond the distal end of the housing a distance corresponding to a wanted insertion depth for the peg when the distal end of the guiding head is moved to the bottom of the second bore, wherein the cassette comprises a number of integral units arrayed in a beam [of the] shaped housing [material].

5. (Twice Amended) A cassette [according to claim 1 implant, characterised in that] for storing and insertion of a solid medicine peg, said cassette comprising at least one unit having a first bore (2) accommodating the medicine peg (3) and having a diameter corresponding to the diameter of the peg (3), a second bore (4) in coaxial extension of the first bore (2) and having a diameter larger than the diameter of the first bore (2), an inserter comprising an inserter shaft (5) fitting into the first bore (2) and a guiding head (6) connected to the inserter shaft (5) in coaxial extension of the inserter shaft and fitting into the second bore, the inserter shaft (5)

having a distal end adjacent to a proximal end of the peg (3) and a proximal end connected to a distal end of the guiding head (6) which forms at its proximal end an anvil (7), the second bore (4) having a length so that the distal end of the inserter shaft (5) is moved to a position extending beyond the distal end of the housing a distance corresponding to a wanted insertion depth for the peg when the distal end of the guiding head is moved to the bottom of the second bore, wherein the cassette comprises a number of integral units arrayed along the periphery of a drum.

6. (Twice Amended) A cassette [according to claim 1, characterised in that] for storing and insertion of a solid medicine peg, said cassette comprising at least one unit having a first bore (2) accommodating the medicine peg (3) and having a diameter corresponding to the diameter of the peg (3), a second bore (4) in coaxial extension of the first bore (2) and having a diameter larger than the diameter of the first bore (2), an inserter comprising an inserter shaft (5) fitting into the first bore (2) and a guiding head (6) connected to the inserter shaft (5) in coaxial extension of the inserter shaft and fitting into the second bore, the inserter shaft (5) having a distal end adjacent to a proximal end of the peg (3) and a proximal end connected to a distal end of the guiding head (6) which forms at its proximal end an anvil (7), the second bore (4) having a length so that the distal end of the inserter shaft (5) is moved to a position extending beyond the distal end of the housing a distance corresponding to a wanted insertion depth for the peg when the distal end of the guiding head is moved

to the bottom of the second bore, wherein the cassette comprises a number of single unit cassettes hinged together to form a cartridge band.